JUN 19 2014

Attachment 4:

510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92.

510(k) Owner
Osseon LLC
2330 Circadian Way
Santa Rosa, CA 95407
Phone: 707-636-5940
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Official Contact
Keith Burger
Director of Research and Development

Device Information

Trade or Proprietary Name:	Osseoflex® SB
Common Name:	Inflatable Bone Tamp
Classification Name:	Primary: Arthroscope Secondary: Cement, Bone Vertebroplasty
Classification Panel:	Orthopedic
Regulation:	Class II per 21CFR §888.1100 Class II per 21CFR §888.3027
Product Code(s)	HRX; NDN
Legally marketed device(s) to which equivalence is claimed	Osseoflex SB Inflatable Bone Tamp K122533
Reason for 510(k)	New Device
Device Description	The Osseoflex® SB is designed for use in balloon kyphoplasty. The balloon serves to create a cavity in the vertebral body, thereby reducing the fracture while still allowing for cement interdigitation. The balloon catheter is the functional part of the device that creates a cavity and reduces the fracture. The balloon catheter provides a conduit through which

the physician can inflate the balloon at the distal end of the catheter. After the bone is disrupted, PMMA is injected through an Osseoflex® needle to fill the previously created void(s).

An access channel is required for Osseoflex® SB placement. The Osseoflex® SB device does not create an access channel; the Osseoflex® SB is designed to follow a pre-existing channel created by an access channel device. The articulating or steering feature of the device assists the clinician in directing the device to the pre-existing channel. The Osseoflex® SB knob can be turned clockwise to aid in directing the distal portion of the device. Turning the knob counter-clockwise will relax the device and allow the device to be returned to its start position. The device should be manipulated only while under fluoroscopic observation with radiographic equipment that provides high quality images.

Intended Use

The Osseoflex® SB is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. This system is to be used with cleared spinal polymethymethacrylate (PMMA) bone cements for use during percutaneous vertebral augmentation, such as kyphoplasty.

Summary of Technological Characteristics of the Additional Size Compared to the Current Size (Predicate)

Characteristic	Additional Size	Current Size (Predicate)
Trade Name, Model	Osseoflex SB, OF-8222	Osseoflex SB, OF-0005
Cannula size	8G	8G
Balloon Inflation Medium	60% Contrast	60% Contrast
Balloon Material	Polyurethane	Polyurethane
Balloon Diameter at nominal volume	15 mm max	15 mm max
Balloon Length at nominal volume	16 mm	15 mm
Balloon Shape	Spherical	Cylindrical
Max inflation pressure	400 psi (27 ATM)	400 psi (27 ATM)

Max inflation volume	2ml	4ml

Summary of Non-Clinical Tests Conducted for Determination of Substantial Equivalence	
Performance Test Summary	
Test Performed	**Acceptance Criteria**
Balloon Profile and Tamp (Catheter) Working Length (TM-003)	• Balloon profile ≤ 3.48 mm (0.137 in) • Balloon catheter working length > 16.5 cm (length of access cannula)
Balloon Compliance (TM-004):	• Balloon working length (L) is 16 mm (reference) at the maximum recommended volume 2 mL. • Balloon diameter (D) is 15 mm maximum at the maximum recommended volume 2 mL. The 15 mm diameter maximum specification is to ensure that the diameter of the balloon will not grow large enough to possibly go through the end plates of the vertebrae.
Maximum Pressure (TM-006)	The inflatable bone tamp exceeds the maximum inflation pressure, 27 atm (~400 psi) without failure.
Bond Tensile Strengths (TM-007)	Bond tensile strength ≥ 15 N (3.37 lbf). The tensile force specification was adopted directly from ISO 10555 (Single Use Intravascular Catheters) requirements. This tensile force maybe applied to the device during use when the balloon is deflated and retracted back through the access cannula.
Balloon Maximum Volume (TM-008)	Maximum inflation volume 2 mL with 95% confidence and 90% reliability.
Balloon Fatigue, Unconstrained (TM-009)	Inflate to maximum recommended volume of 2 mL, hold for 30 seconds / deflate; without leaks for 20 cycles.
Balloon Inflation, Deflation Time (TM-010)	The Osseoflex SB 2ml samples deflation times to be clinically equivalent to other marketed inflatable bone tamps.
Summary of Clinical Tests Conducted for Determination of Substantial Equivalence	
N/A – No clinical test were conducted for this submission	
Conclusions Drawn from Non-Clinical and Clinical Data	
The results of the non-clinical tests show that the Osseoflex SB, 2ml meet or exceed all performance requirements, and are substantially equivalent to the predicate device.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 19, 2014

Osseon LLC
% Mr. Keith Burger
Director of Research and Development
2330 Circadian Way
Santa Rosa, California 95407

Re: K140937
Trade/Device Name: Osseoflex SB
Regulation Number: 21 CFR 888.3027
Regulation Name: Polymethylmethacrylate (PMMA) bone cement
Regulatory Class: Class II
Product Code: NDN, HRX
Dated: May 30, 2014
Received: June 2, 2014

Dear Mr. Burger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140937

Device Name
Osseoflex SB

Indications for Use *(Describe)*
The Osseoflex® SB is intended to be used for the reduction and fixation of fractures and/or creation of a void in cancellous bone in the spine. This includes use during percutaneous vertebral augmentation. This system is to be used with cleared spinal polymethymethacrylate (PMMA) bone cements for use during percutaneous vertebral augmentation, such as kyphoplasty.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Laurence D. Coyne -A

(Division Sign-Off)
Division of Orthopedic Devices
510(k) Number: K140937

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